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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/540,446

05/08/2006

Teruo Nishida

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EXAMINER

UNDERDAHL, THANE E

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

10/15/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/540,446	Applicant(s) NISHIDA ET AL.	
	Examiner THANE UNDERDAHL	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/17/08.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/16/05</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's response, with traverse, to the Restriction/Election requirement filed on 7/17/08 is acknowledged. The applicant elected Group I which includes claims 1-7.

Applicant alleges that there would be no burden on the examiner in examining all of the claims at once, relying on M.P.E.P. §802.02. Chapter 800, however, is limited to a discussion of the subject of restriction and double patenting under Title 35 of the United States Code and Title 37 of the Code of Federal Regulations as it relates to national applications filed under 35 U.S.C. 111(a). The discussion of unity of invention under the Patent Cooperation Treaty Articles and Rules as it is applied as an International Searching Authority, International Preliminary Examining Authority, and in applications entering the National Stage under 35 U.S.C. 371 as a Designated or Elected Office in the U.S. Patent and Trademark Office is covered in M.P.E.P. §1850 and is dictated by PCT Rules 13.1 and 13.2. See M.P.E.P. §801. Burden is not a consideration in a finding of lack of inventive unity; rather, according to M.P.E.P. §1850, the only consideration is whether the inventions share a special technical feature.

The expression "special technical feature" refers to those features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. Thus, a feature found in the prior art cannot be considered to be a special technical feature. As mentioned in the Restriction requirement mailed, 6/23/08, the special technical feature of claim 1 of this application was found in the article cited by Aucoin et al. and thus the finding of lack of unity is proper.

Therefore, the Restriction requirement is therefore made FINAL and the elected species and the claims they include will now be examined on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Aucoin et al. (J. Biomater. Sci. Polymer. Edn, 2002). in light of support of the Pubmed citation of this article.

The Pubmed citation of this article is included to show that the article was available to the public as of 8/6/02, which is the EDAT date (also known as the entrez

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date) or the date the article was added to the Pubmed database, thus making the article available more than one year prior to the filing of the PCT on 12/24/03 and thus one year prior to the U.S. filing date. In this case the effective U.S. Filing date is 12/14/03 which is the date the PCT application was filed (M.P.E.P. § 1801 and 1896) and since the priority document cited is not a U.S. Application.

The Applicant is reminded that if one discloses his or her own work more than 1 year before the filing of the patent application, that person is barred from obtaining a patent. In re Katz, 687 F.2d 450, 454, 215 USPQ 14, 17 (CCPA 1982). **The 1-year time bar is measured from the U.S. filing date.** Thus, applicant will be barred from obtaining a patent if the public came into possession of the invention on a date before the 1-year grace period ending with the U.S. filing date. It does not matter how the public came into possession of the invention. Public possession could occur by a public use, public sale, a publication, a patent or any combination of these. In addition, the prior art need not be identical to the claimed invention but will bar patentability if it is an obvious variant thereof. In re Foster, 343 F.2d 980, 145 USPQ 166 (CCPA 1966). See MPEP § 706.02 regarding the effective U.S. filing date of an application.

Claims 1-7 are drawn to compositions containing effective amounts of the peptide PHSRN (SEQ ID #1). Claims 1, 2, and 6 include the limitation of "that is allowable as a medical drug". This limitation is an intended use and given no patentable weight since the limitations in the claims provide a structurally complete invention and simply stating that the peptide is "allowable as a medical drug" does not add any further structural limitations to the composition (M.P.E.P. § 2111.02 II). The

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same rationale applies to the limitations of claim 2-5 where the composition is used to treat various corneal disorders. Since the claims are drawn to a composition and not a method of treatment these limitations do not provide any further structural limitations to define the composition and as such are given no patentable weight.

Aucoin et al. teach an ophthalmological composition containing the peptide PHSRN bound to a synthetic keratoprosthesis which is an ophthalmological composition for cornea replacement (See Abstract). Aucoin et al. teach that the amount of dose or PHSRN bound to the keratoprosthesis can be adjusted to adjust the adhesion of human corneal epithelial cells to the surface (pg 452 "In vitro cell adhesion" and Figure 1). Therefore the reference anticipates claims 1-7.

In summary no claims, as written, are allowed for this application.

In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571)

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272-9042. The examiner can normally be reached Monday through Thursday, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thane Underdahl
Art Unit 1651

/Leon B Lankford/
Primary Examiner, Art Unit 1651